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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,715	08/05/2003	Adel B. Korkor	155.015	8917
23598	7590	01/27/2006	EXAMINER	
BOYLE FREDRICKSON NEWHOLM STEIN & GRATZ, S.C. 250 E. WISCONSIN AVENUE SUITE 1030 MILWAUKEE, WI 53202			AHMED, AAMER S	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,715

Applicant(s)

KORKOR ET AL.

Examiner

Aamer S. Ahmed

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/05/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the species of Group III: Figure 13, including claims 1-37, without traverse in the reply filed on November 28, 2005 is acknowledged.

Specification

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Claim 7 is written to depend from claim 7. For the purposes of examination, it will be assumed that claim 7 refers to and depends from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 and 22-32 rejected under 35 U.S.C. 102(b) as being anticipated by Weikl et al U.S. Patent Number 4,451,256.

As to claims 1, 2, 13 and 22, Weikl et al discloses a catheter introducer comprising an elongate, hollow body defining a lumen having a distal end and a proximal end (1); a hub (64) disposed at the proximate end, the hub (64) being configured to permit communication between the hub (64) and the body (1); and an expandable tip on the distal end, the expandable tip including a sidewall that is continuous and non-convoluted in an unexpanded state and including an opening axially extending there through and configured upon insertion of a device having a larger outer diameter than the inner diameter of the expandable tip, to permit passage of the device there through, the expandable tip being configured to expand commensurately with a difference between the outer diameter of the device and the inner diameter of the expandable tip, (col. 3 line 56 – col. 4 line 12), wherein the expandable tip comprises a tubular wall having an axially extending weakened portion formed from (1) at least two axially aligned slit segments and (2) at least two axially aligned segments that are strengthened when compared to the slit segments, one of the strengthened segments being positioned between two of the slit segments and another of the strengthened segments being formed between a distal-most slit segment and a distal end of the expandable tip (see figure 15), at least one of the strengthened segments comprising a scored segment having a wall thickness greater than a thickness of the expandable tip wall at the slit segments but less than a thickness of the remainder of the expandable tip wall (col. 6 line15).

As to claims 3-12, 14-16, 23-24 and 29-32 Weikl et al teaches that the slit segments and the scored segments (see figure 6) are formed in an outer peripheral surface of the expandable tip wall, that the body is formed from a material comprising polymeric material (col. 5 line 62), that the weakened portion of the expandable tip has at least four axially aligned slit segment (see figure 6), that are offset from one another by about 180 degrees (see figure 6) and wherein the slit segments extend at least essentially at least 99% through the depth of the expandable tip wall and the at least one of the strengthened segments comprises a scored segment extending through about 10% of the depth of the expandable tip wall, wherein the scored segment extends through about 20% of the depth of the expandable tip wall (see figure 6) and wherein the body is tapered such that the distal end is narrower than the proximal end (see figure 6).

As to claims 25-28, Weikl et al discloses that the slit segment (17) is a first slit segment, and wherein the weakened portion of the tubular wall further comprises a second slit segment that it axially aligned with the first slit segment an the scored segments and that it located between the second scored segment and the proximal end of the tip (see figure 6); and wherein the weakened portion of the tubular wall includes at least two slit segments and at least two scored segments which are disposed in an alternating aligned abutting relationship with one another (see figure 6); and wherein the tubular wall has a second weakened portion and which is circumferentially offset from the first weakened portion; and wherein the two weakened portions are offset from one another by about 180 degrees (see figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-21 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl et al in view of Gellman U.S. Patent 5,057,083.

As to claims 17-21 and 33-37, Weigl et al discloses a method of inserting a medical device having a larger outer diameter than an inner diameter of a catheter tip of a catheter introducer through an opening in the catheter tip, the method comprising cannulating a vein or artery with the catheter introducer, the catheter introducer including an expandable tip on a distal end thereof, the expandable tip including a body including an outer surface defining a lumen and having a distal end and a proximate end; and; an expandable tip on the distal end, the expandable tip including an opening axially extending there through and an axially extending weakened

portion formed from at least two axially slit segment and at least two axially aligned segments that are strengthened when compared to the slit segments, one of the strengthened segments being positioned between the slit segments and another of the strengthened segments being formed between a distal-most slit segment and the distal end of the expandable tip, and at least one slit segment and at least first and second scored segments that are axially aligned with each other and with the slit segment, the first scored segment positioned between the slit segment and a proximal end of the expandable tip, and the second scored segment extends from the slit segment to a distal end of the expandable tip; removing the needle from the catheter introducer; inserting a medical device into the body, the device having a larger diameter than a minimum inner diameter of the expandable tip; inserting the medical device through the lumen of the body; and inserting the medical device through the opening of the expandable tip, thereby expanding the expandable tip as a result of the insertion of the medical device through the tip; and then removing the catheter introducer from the patient's body while leaving the device in place (col. 4 lines 20-59); and wherein the expanding step comprises splitting the distal end of the expandable tip at least one of the weakened portion and expanding a width of at least one of the slit segment (see figure 6)

Weigl et al fails to disclose a cannulating needle, a guidewire nor a PICC line

Gellman discloses a similar method including the step of cannulating using a needle (col. 2 line 56) a guide wire (14) and PICC line (10).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Weigl et al by incorporating the needle, guidewire and

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PICC line steps as disclosed by Gellman in order to provide a vessel dilator having a tip construction which facilitates smooth entry of the dilator into the blood vessel (col. 2 line 17).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5527292 A Adams; Daniel O. et al.
US 5183646 A Anderson; Lawrence B. et al.
US 6592569 B2 Bigus; Steve et al.
US 5443449 A Buelna; Terrance J.
US 5707359 A Bufalini; Bruno
US 5683378 A Christy; William J.
US 6246914 B1 de la Rama; Alan et al.
US 5741429 A Donadio, III; James V. et al.
US 20010039430 A1 Dubrul, William R. et al.
US 6494893 B2 Dubrul; William R. et al.
US 6030364 A Durgin; Russ et al.
US 6197016 B1 Fourkas; Michael G. et al.
US 6808520 B1 Fourkas; Michael G. et al.
US 4738666 A Fuqua; Clark R.
US 6918888 B2 Gershowitz; Arthur D.
US 20030236545 A1 Gilson, Paul
US 4921479 A Grayzel; Joseph
US 5053009 A Herzberg; Wolfgang
US 5201756 A Horzewski; Michael J. et al.
US 20050182475 A1 Jen, Jimmy et al.
US 6183443 B1 Kratoska; William F. et al.
US 20050216047 A1 Kumoyama, Kenichi et al.
US 20050149105 A1 Leeftang, Stephen A. et al.
US 5997508 A Lunn; Peter A. et al.
US 20010012946 A1 MacKenzie, Andrew J. et al.
US 20040093003 A1 MacKenzie, Andrew J. et al.
US 6692462 B2 Mackenzie; Andrew J. et al.
US 5447503 A Miller; Jay F.
US 6761703 B2 Miller; Paul J. et al.
US 4801297 A Mueller; Richard L.
US 20050125021 A1 Nance, Edward J. et al.
US 6162236 A Osada; Toshihiko
US 5752937 A Otten; Lynn M. et al.
US 5944691 A Querns; Stephen et al.
US 3877429 A Rasumoff; David L.

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US 5573520 A Schwartz; Robert S. et al.
US 6569145 B1 Shmulewitz; Ascher et al.
US 5395341 A Slater; Andrea T.
US 5738666 A Watson; David A. et al.
US 4952359 A Wells; Stanley C.
US 4776846 A Wells; Stanley C.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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